Harm reduction regulation



Clive Bates Action on Smoking and Health United Kingdom

Action on Smoking and Health

C<mark>o</mark>verage

- European Union
- WHO Framework Convention
- Harm reduction in practice

-Rapin raduction: 11 May 2001

EU tobacco directive

- · EU directive not yet finalised
 - Regulates T, N, CO yields
 - Requires pack labelling with yields
 - Health warnings
 - Ingredient disclosure by brand to be made public
 - Health claims not permitted
 - Oral tobacco banned except Sweden & Finland
 - Technical committee (warning texts, tracability, measurement methodologies)
 - Commission report with terms of reference

Harn reduction: 11 May 2001

WHO FCTC

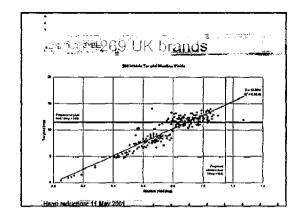
- · In negotiation -- to be agreed by 2003
- · "Chair's text" produced in January 2001
- · Framework with specifics, including:
 - Labelling & descriptors
 - Product modification
 - Disclosures
 - Advertising
 - -- Smuggling
- · www.ash.org.uk/?international for more detail

Harm radic lion: 11 May 2001

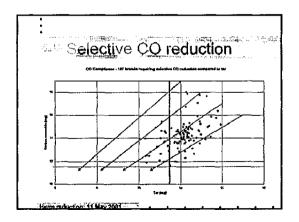
Product modification: EU article 3

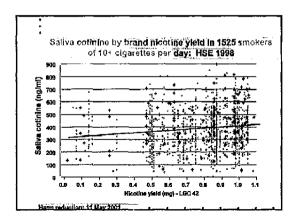
- · Tar yield ISO 4387
- <10mg (currently <12mg)
- · Nicotine yield ISO 10315
 - <img (currently no limit)
- CO yield ISO 8485
- <10mg (currently no limit)
- Tolerance and accuracy ISO 8243
- +/- 15%
- · Applies from 1st Jan 2004
- Applies to EU exports from 1st Jan 2007

Name made Man of Unit 2004



1



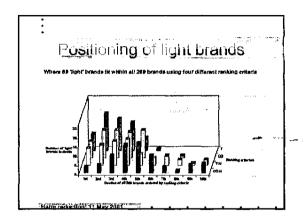


Product modification: FCTC

(Regulation of contents of tobacco products)

G.1.(b) adoption of standards for the regulation of the contents of tobacco products, including standards for testing and measuring, designing, manufacturing and processing such products, and cooperation in the development and harmonization of such standards under the auspices of the World Health Organization;

Harm reduction: \$1 May 2001



Ingredients: EU & FCTC

ΕU

- Requirement to submit a list of ingredients in use by brand
- Must give reason for use, known addictive effects, and toxicology
- Information to be made public
- But due account of trade secrets

FOTO

[enforce] tobaccoproduct disclosures by all manufacturers, including all ingredients and additives, and major constituents of tobacco smoke, and promotion of availability of such information to the public.

Harm reduction: 11 May 2001

:Des**gri**ptors: EU **Article 7**

[... by 30 Sept 2003] texts, names, trademarks and figurative or other signs suggesting that a particular tobacco product is less harmful than others shall not be used on the packaging of tobacco products.

- Intended to ban light/mild branding (supported in preamble)
- 96 out of 269 brands (36%) on UK market affected
- Trade-related challenge expected from Japan

Harm reduction: 11 Way 2001

_ ⊵scriptors: FCTC

(Packaging and labelling)

- G.1.(d) adoption of appropriate measures to ensure that:
- (i) the terms "tow tar", "light", "ultra light", "mild" or any other similar term that has the aim or the direct or indirect effect of conveying the impression that a particular tobacco product is less harmful than others are not used on any unit packet or package of tobacco products:

Samurachicition 11 May 2001

Descriptors: FCTC

- (ii) tobacco packaging and labelling does not otherwise promote a tobacco product by any means that are false, misleading or deceptive or that are likely to create an erroneous impression about its characteristics, health effects, hazards or emissions:
- [(iii) tracking and tracing]

Harm reduction 11 Key 2001

ے Labelling: EU article 5 ہ

- The tar, nicotine, and carbon monoxide yields of cigarettes [...] shall be printed on one side of the cigarette packet [...]
- · Health warnings (not discussed here)

Harm mitselfon, 44 May 2004

ં ં**La**belling: FCTC

(iv) each unit packet or package of tobacco products carries a general health warning, including a picture or pictogram illustrating the harmful consequences of tobacco consumption, in accordance with Annex IINSERTI; these warnings shall:

Harm reduction: 11 May 2001

Labelling; FCIC continued...

- clearly indicate the prohibition of sales of tobacco products to persons under the age of 18:
- (2) provide clear information about the toxic contents of the tobacco product, specifically tar, nicotine and carbon monoxide, including actual measurements of smoke yields.
- (3) appear in the principal language or languages of the country in whose territory the product is placed on the market.

Harm reduction: 11 May 2001

, Oral tobacco: EU article 8

- Tobacco for oral use does not include smoking or chewing tobacco
- Oral tobacco prohibited in the EU
 - Exception for Sweden and Finland
 - Sweden has half EU average tobaccorelated mortality

Harro recketton: 11 May 2001

- EU report: article 11

- · Article 11 requires report by Dec 2004
- · Assisted by scientific and technical experts
 - Further yield reductions
 - Links between yields
 - Improvements in health warnings
 - Methodologies for more realistically assessing toxic exposure and harm
 - Evaluation of tobacco products with potential to reduce harm

 - Addictive effects of ingredients
 Testing for other smoke constituents
 - Appropriate loxicological data
 - Standards for products other than cigarettes

Observations

- · Gap between science and law
- · Underlying mechanism misunderstood
- · Yields seen as meaningful
 - Confusion about alternative
 - Reluctance to advocate "less bad",
 - "Perfect" the enemy of "better" leading to victory
- · Internal contradictions
- · Perverse regulation (oral tobacco)

"Harm reduction; real issues

- · Light branding
- · Oral tobacco
- · New indications for NRT
- · Synthetic nicotine products lifestyle branded
- Novel tobacco products...

Direction: purity standards

- · Assume users will seek and find the nicotine they want
- · Reduce harm associated with delivery system
- · Regulatory pressure to force manufacturing changes
 - Reduce toxins (CO, nitrosamines, BaP, NOx etc) per unit
 - Possible evolution of nicotine delivery through combustion > heating > extracts > distillates > non-
- But CONTROL nicotine manipulation
 - Additives, free fraction, vapour, initial puffs, smoke particle size

farm middle of the confer

